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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,495	06/28/2001	Shinichi Yamada	057250903	5364

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/24/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,495

Applicant(s)

YAMADA ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Preliminary Amendment filed on November 9, 2001.

Claims 1-18 have been cancelled and claims 19- 81 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of treating hair, does not reasonably provide enablement for method of "*protecting keratinous materials from physical and chemical attacks*". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claim is rejected under 35 U.S.C. § 112, first paragraph, because the enablement for methods of protection of keratinous materials from physical and chemical attacks lacks support from the applicant's specification or prior art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

The burden of enabling the protection from physical or chemical attacks as claimed (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen the keratinous materials susceptible to such conditions. In the instant case, the specification does not provide guidance as to how

one skilled in the art would go about protecting the keratinous materials from those conditions within the scope of the presently claimed invention. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in protecting the keratinous materials. The specification fails to enable "protection", and undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method for the protection of keratinous materials.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "a C16 – C40 fatty acid chosen from 18-methyleicosanoic acid, hydroxy acids, vitamins, panthenol and fatty esters" is vague and confusing, and such fatty acids in the claim limitation lack the support from the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 19, 20, 57, 58, 62, 64, 65, 70, 74, 75, and 80 are rejected under 35

U.S.C. 102~~(a), (b), and~~ (e) as being anticipated by Bergmann (US 6110450).

The broadest claims in the instant case claim a composition comprising ceramide, fatty alcohol, and cationic surfactant in a cosmetically acceptable medium, and a method of making and using the same.

Bergmann, discussed above, discloses hair care composition comprising at least one ceramide and/or glycosphingolipid in a cosmetically acceptable medium. See abstract. Example 2 shows a formulation comprising oleoyldihydrosphingosine, cationic surfactants (components 1 and 4) and fatty alcohols (components 5 and 6). The preparation of the example composition is also disclosed, meeting instant claims 57, 58, and 62. The methods for treating and protecting hair in instant claims 64, 65, 70, 74, 75, and 80 are inherently practiced by in the disclosure.

2. Claims 19, 20, 52, 54, 56, 57, 58, 62, 64, 65, 70, 74, 75, and 80 are rejected under 35 U.S.C. 102~~(a), (b), and (e)~~ as being anticipated by Dubief et al (US 5679357) ("Dubief ('357)").

Dubief ('357) discloses a hair care composition comprising ceramide, cationic surfactant, and fatty alcohols, in aqueous medium. See Example 4. The method of

using the composition for treatment and protection of hair is inherent in the composition.
See col. 1, lines 4 – 62.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied references have a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

1. Claims 19- 29 and 32-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maubru (US 6312674 B1) in view of Bergmann (US 6110450) and Dubief et al. (US 6120757) ("Dubief").

Maubru teaches oxidizing composition for bleaching or permanent reshaping hair, wherein the composition comprises ceramides disclosed in col. 3, line 21 – col. 16, line 13. It is noted that oxidizing composition is used in "fixing step" in the permanent waving/straightening process. See col. 1, lines 1-29. Adding cationic polymers as a cosmetic additive is also suggested. See col. 5, lines 54 – 58; instant claim 19, 57, 64, and 74. The reference further teaches that the invention may contain other additives that are "known for their use in oxidizing compositions for bleaching or permanent reshaping of the hair", and that the invention may be modified in the form of shampoo. See col. 5, lines 44 – 49. The claimed process of treating is necessarily practiced when the composition is used according to the teaching in the prior art.

Maubru fails to teach fatty alcohol or the specific cationic polymers of instant claims.

Bergmann, discussed above, teaches hair treatment composition comprising ceramides and phytantriol, which is useful for hair treatment. See abstract. The reference teaches that using cationic polymers or ceramides for hair treatment is well known in the art. See col. 1, line 16 – 48. The ceramide of instant claims are used in Bergmann. See col. 2, line 26 – col. 5, line 39. Adding cationic quaternary ammonium surfactant, fatty alcohol, and/or vitamins is also suggested. See col. 2, line 3 – 10; col. 5, lines 40 - 43; col. 6, lines 27 – 34. See instant claims 35 and 55. The invention may be used with permanent waving reducing or “fixing” agents. See col. 6, line 50 – col. 7, line 26. See also Examples 1 and 2.

Bergmann fails to teach the specific quaternary ammonium surfactants of instant claims.

Dubief teaches aqueous dispersion comprising quaternary ammonium surfactants, which is useful for hair cosmetic compositions. See col. 4, line 51 – col. 6, line 2; see instant claims 35-51. The reference discloses that the invention can be used in permanent waving or straightening products or for washing or rinsing. See col. 6, lines 50 – 58.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown

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by the recited teachings, the instant claims define nothing more than the concomitant use of hair care ingredients. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

In this case, given the general teaching in Maubru that conventional additives for oxidizing composition for hair can be employed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Bergmann and Restle for specific additives such as fatty alcohol and quaternary ammonium surfactants. The motivation to combine the ingredients to successfully formulate a hair composition for topical application is found in the teachings the prior arts that these are old and well known for hair treatment purposes. See In re Kerhoven. Nothing nonobvious or unexpected is seen in combining conventional ingredients used for same purposes. See MPEP § 718.02.

2. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maubru, Bergmann, and Dubief as applied to claims 19-29 and 32-81 above, and further in view of Critchley et al. (US 5198210) ("Critchley").

Maubru, Bergmann, and Dubief are discussed above. The combined references fail to teach isocetyl or isostearyl alcohol.

Critchley teaches cosmetic compositions for skin, hair and nails which contains synthetic ceramides and emollients such as isocetyl alcohol, stearyl alcohol and cetyl alcohol. See col. 1, line 11 – col. 6, line 51; col. 10, lines 44 – 61.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Dubief I by substituting the stearyl alcohol and cetyl alcohol with isocetyl alcohol, as suggested by Critchley, because of the expectation of successfully producing hair care products with similar emolliency effects.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of Maubru in view of Bergmann, Dubief, and Critchley. (US 6120757)

The Maubru patent, discussed above, claims oxidative composition comprising the ceramides of instant claims 19-29, and process of treating hair. The invention as claimed fails to disclose adding fatty alcohol, and indicates that cationic polymers are excluded from the claimed invention.

Examiner notes that those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). In this case, the specification of the Maubru patent teaches that cationic polymers in fact can be used in the invention. See col. 2, line 3 – 10. The negative limitation to specifically exclude cationic polymers is thus viewed as a boundary which distinguishes the Maubru patent from the prior arts and does not teach away a skilled worker from adding a cationic polymer.

Bergmann, Dubief, and Critchley are discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the claimed invention in the Maubru patent by adding cationic surfactants and fatty alcohols as suggested by Bergmann, Dubief, and Critchley, because of the expectation of successfully producing a hair treatment composition. The motivation to combine the references flow from the fact that the disclosed components in the references are all old, well known, and used for the same purposes. See In re Kerhoven.

Conclusion

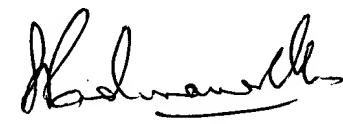
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
September 21, 2002



SREENI PADMANABHAN
PRIMARY EXAMINER

9/21/02